



**UNITED STATES DEPARTMENT OF COMMERCE**  
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Advisory Action

Application No.

08/950,542

Applicant(s)

Bachovchin

Examiner

David Lukton

Group Art Unit

~~1051~~

THE PERIOD FOR RESPONSE: [check only a) or b)]

1653

- a) expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- X Appellant's Brief is due two months from the date of the Notice of Appeal filed on Dec 27, 1999 (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on \_\_\_\_\_ has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

- X The proposed amendment(s):

- X will be entered upon filing of a Notice of Appeal and an Appeal Brief.

will not be entered because:

- they raise new issues that would require further consideration and/or search. (See note below).
- they raise the issue of new matter. (See note below).
- they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

Applicant's response has overcome the following rejection(s):

Newly proposed or amended claims \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

- X The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see accompanying sheets

The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- X For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: none

Claims objected to: \_\_\_\_\_

Claims rejected: 35-51

The proposed drawing correction filed on \_\_\_\_\_ has \_\_\_\_\_ has not been approved by the Examiner.

Advisory Action

Claims 35-51 are rejected under 35 U.S.C. §103 as being unpatentable over Bachovchin (*J. Biol. Chem.* **265**, 3738, 1990).

Applicants have argued that the passage on page 3743 would not be interpreted by a chemist as a statement that fraction was obtained which was absolutely and unequivocally enriched in the L-isomer. Applicants assertion is not challenged, but neither is such an unequivocal statement required. The statement by the authors that of an interpretation of a result. If a chemist stumbles onto the truth fortuitously, and reports in a publication that he obtained compound "X", such a report can be sufficient to bar a later scientist from being granted a monopoly on compound "X", even if the level of sophistication of the experiments carried out by the later scientist is much higher than that of the first. To take it a step further, if a scientist published a structure of compound "X", and it turned out that the structure he had determined was not correct, a later chemist would be barred from claiming the published structure for a compound "Y", even if the later chemist were entirely correct in his structure determination. To take another example that is closer to the case at hand, if a first chemist publishes a structure of compound "X", and he later turns out to be absolutely correct, a second chemist would not be granted a

that he was not absolutely certain of the structure.

Applicants have argued that the *J. Biol. Chem.* article should be considered in its entirety. Yet applicants have pointed to no passage in the article which would "teach away" from a 95% enriched mixture of Ala-BoroPro. Thus, while one should perhaps give weight to contradictory statements in a disclosure, applicants have not pointed to any. While it may be appropriate to consider the teachings of a disclosure as a whole, there is also a significant Court ruling, *In re Baird*, which stands in part for the proposition that the disclosure as a whole is not sufficient to make a case for a §103 rejection; that an examiner should look for specific examples in order to determine preferred embodiments. Thus, the reference discloses that a 95% stereoisomer enriched mixture of Ala-BoroPro was probably obtained.

Applicants have next referred to Gutheil (*Biochemistry* **32**, 8723, 1993). The examiner confirms that figure 1 of the publication refers to *trans*- Pro-BoroPro, and that on page 8728, col 1, the following statement can be found: "The inactive material is the cyclic structure in which the N-terminal nitrogen atom forms a covalent bond with the boron atom...".

Applicants have argued that the presumption of enablement is not to be conferred upon a statement in a scientific publication. However, whether Court rulings stand for the proposition that statements in scientific journals are enabling, or that statements in scientific

law mandates imposing on scientific publications the presumption of error, applicants should cite such a Court ruling.

If applicants have made a contribution beyond what is disclosed in the *J. Biol. Chem.* article, it is not in asserting the existence of a 95% stereoisomer enriched mixture of Ala-BoroPro, but in identifying a means to obtain it, and in providing spectral evidence for it. But the 95% enriched mixture of Ala-BoroPro *per se* has already been disclosed, irrespective of what evidence led to that disclosure. Were it not for new matter, applicants could claim the Ala-BoroPro mixture, not by structure or by name or *per cent* stereoisomeric purity, but by a product-by-process description, together with NMR data.

As the claims stand, however, the rejection is maintained.

✱

Claims 35-51 are rejected under 35 U.S.C. §103 as being unpatentable over Bachovchin (USP 4,935,493) or Bachovchin (WO 89/03223) or Flentke (*Proc Natl Acad Sci* **88**, 1556, 1991).

Applicants have argued that Bachovchin ('493) does not form the basis for a proper §102 rejection. This point is not in dispute. Applicants have also argued that the reference does not teach a method for separating diastereomers. However, the instant claims are not drawn to a method of such; they are drawn to mixtures of compounds. As indicated

encompass, for example, a stoichiometry of 10,000,000:1 of the L-isomer to the D-isomer.

As it happens, it is not uncommon for there to be trace amounts of an undesired stereoisomer in chiral molecules that are synthesized, obtained commercially, or isolated from a plant or animal. Thus, in many cases, 100% stereochemical purity is often more of an ideal than a reality, when the point is emphasized that 99.999999% stereochemical purity is distinct from 100% stereochemical purity. In other words, the instant claims could, for all intents and purposes, be viewed as claims to the "all-L" stereoisomer. Given that L-amino acids are the most commonly used, and usually the most active biologically, the question of obviousness could be posed in the following way. If a reference discloses a peptide represented as  $X^1-X^2-X^3-X^4-X^5$  in which  $X^1$ ,  $X^2$ ,  $X^3$  and  $X^4$  are L-amino acids, and  $X^5$  is a 50/50 mixture of D- and L-isomers, which is more obvious, the "all-L" peptide, or the 80%-L, 20%-D peptide?

The rejection is maintained.

\*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800